K072913 Page 1/2

Hologic, Inc.
6100 Technology Center Drive, Indianapolis, IN 46278 USA
Main: +1.800.650.2169 Fax: +1.317.344.7600

510(k) Summary

OWNER/OPERATOR:

Firm:	Hologic, Inc. – Suros Division
Address:	6100 Technology Center Drive Indianapolis, IN 46278
Phone #:	317-344-7500
Fax #:	317-344-7697
Registration #:	3003862400

CONTACT: Paula A. Gray
Senior Quality & Regulatory Consultant
Hologic, Inc. – Suros Division
6100 Technology Center Drive
Indianapolis, IN 46278
Phone: 317-344-7687

JAN - 4 2008

DATE: 12/06/2007

DEVICE NAME:

Classification Name:	Marker, Implantable Radiographic
Common/Usual Name:	Tissue Site Marking System
Proprietary Name:	SeCurMark Biopsy Site Identification System
Device Class:	Class II
Description	Implantable Clip
Number	NEU
21 CFR Ref.	878.4300
Performance Standards	No applicable performance standards established

PREDICATE DEVICES:

510(k)-Number	Device Name	Device Manufacturer	Location
K062528	Tissue Site Marking System	Hologic, Inc. – Suros Division	Indianapolis, IN
K042296	BiomarC	Carbon Medical Technologies, Inc.	St. Paul, MN

HOLOGIC Clarity of Vision

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DEVICE DESCRIPTION AND CHARACTERISTICS:

The SeCurMark family of Tissue Site Marking Systems is composed of two components:

- an implantable component, composed of a bioabsorbable and permanent component, and
- a deployment device utilized for placement of the implantable component at the site of interest.

This family of devices is intended for use with the manual method of deployment under the following imaging modalities: ultrasound, x-ray, magnetic resonance, and direct visualization. The device is intended for single patient use only.

INTENDED USE:

The Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

SUBSTANTIAL EQUIVALENCE:

Verification and validation testing has been conducted as part of the Suros divisions design control process and has proven that the SeCurMark family of devices is substantially equivalent to the predicates devices and is safe and effective for use.

CONCLUSION:

Based on the information presented in this 510(k) submission, the SeCurMark Biopsy Site Identification System is substantially equivalent to the presently marketed predicate devices. No new safety or efficacy questions or risks are raised with the SeCurMark Biopsy System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2008

Suros Surgical Systems, Inc.
% Ms. Paula A. Gray
Senior Quality & Regulatory
Consultant
6100 Technology Center Drive
Indianapolis, Indiana 46278

Re: K072913
Trade/Device Name: SeCurMark Biopsy Site Identification System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: December 6, 2007
Received: December 7, 2007

Dear Ms. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072913

Device Name: SeCurMark Biopsy Site Identification System

Indications for Use:

The SeCurMark Tissue Site Marking System is indicated for the permanent radiographic marking of sites in soft tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072913